UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/699,351	10/31/2003	Ronald James Jandacek	9129L	2523

27752 7590 05/16/2007

THE PROCTER & GAMBLE COMPANY
INTELLECTUAL PROPERTY DIVISION - WEST BLDG.
WINTON HILL BUSINESS CENTER - BOX 412
6250 CENTER HILL AVENUE
CINCINNATI, OH 45224

EXAMINER	
GEMBEH, SHIRLEY V	
ART UNIT	**PAPER NUMBER**
1614	

MAIL DATE	DELIVERY MODE
05/16/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/699,351	JANDACEK ET AL.	
	Examiner	Art Unit	
	Shirley V. Gembeh	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 February 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-78* is/are pending in the application.

4a) Of the above claim(s) *37-70 and 72-78* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-36 and 71* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *5/25/05;6/17/04;2/6/04*
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

The response filed **February 15, 2007** presents remarks and arguments to the office action mailed **7/5/2006**. Applicants' request for reconsideration of the rejection of claims in the last office action has been considered.

Applicants' arguments, filed, have been fully considered but they are not deemed to be persuasive. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Information Disclosure Statement

The information disclosure statement (IDS) submitted on 5/05/07; 6/17, 2004 and 2/06/04 have been received and acknowledged.

Status of claims

Claims 1-36 and 71 are pending in this office action.

Claims 37-70 and 72-78 are withdrawn as non-elected specie.

Maintained Claim Rejections - 35 USC § 112

Applicant argues that the grouping of claims 3-6 is inappropriate with regards to the rejection, stating claims 3-6 do not have the limitation of "at least about".

In response, claims 3-6 depend from claim 1 and if a claim has a limitation that is rejected, the dependent claims are inclusive of the rejection.

Next, in other to clarify the rejection it has been written more clearly below as pertained to claims 1-10, 13-14, 16, 19-20, 22 and 25 as originally rejected. Upon further consideration other claims have been added to the rejection.

New Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-10, 13-14, 16, 19-20, 22, 25-36 and 71 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The term "from about", "at least about" are not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, one of ordinary skill in the art would not be reasonably apprised of the scope of the invention, because one of skill will not be able to determine which term is in control. The claims lack "from" (a lower limit) or "about"(broadening limitation, both higher and lower) controls the metes and bounds of the phrase "from about". Regarding "at least" (a lower limit) or about "(broadening limitation, both higher and lower) controls the metes and bounds of the phrase "at least about".

Maintained *Claim Rejections - 35 USC § 103*

Examiner in-avertedly typed in methods in the explanation/discussion section of the rejection in the last office action.

I. Claims 1-12 remain rejected under 35 U.S.C. 103(a) as being unpatentable over de Smidt et al. US 6,703,369 B1 in view of Maeder et al. US 6,730,319 B2.

Applicant argues, that the cited references do not teach the stiffening agents in particular ratio of stiffening agents to lipase as cited in the instant claim 1 and thus failing to teach every element in the instant claims 1-12.

In response, the wide range as taught by de Smidt falls within the range claimed. Applicant has not shown otherwise that this ratio has a specific effect or an unexpected result. In response to the references failing to teach every element, the claims call for a stiffening agent wherein the stiffening agent is R-OR, contains 14-24 carbons, a lipase inhibitor, in a ratio, which when calculated from the prior art is within the claimed invention. For example the stiffening agent is taught in the amount of 0.5-90% and the lipase inhibitor is taught in the amount of 1-50%. These ranges support ratios that are clearly within the instant claims and of one of ordinary skill in the art would be motivated to determine the amount of each ingredient to be used to get the maximum effect. Thus the argument is unpersuasive.

II. Claims 13-24 remain rejected under 35 U.S.C. 103(a) as being as unpatentable over de Smidt et al. US 6,703,369 B1 in view of Maeder et al. US 6,730,319 B2.

The same argument above with regards to claims 1-12 is applied to claims 13-24. With traversal that de Smidt only teaches compositions including lipase inhibitors in combination with fatty acid esters as a second component.

In response to this, the claims recite "a composition comprising" that is it can have other compounds or agents. Thus argument is unpersuasive.

III. Claims 25-30 remain rejected under 35 U.S.C. 103(a) as being as unpatentable over de Smidt et al. US 6,703,369 B1 in view of Maeder et al. US 6,730,319 B2. Regarding claims 25-30, Applicant argues that "There is no teaching or suggestion in either de Smidt et al. or Maeder et al. to use any sort of stiffening agent to stiffen lipophillic substances in the gastrointestinal tract. Both de Smidt and Maeder require a combination of lipase inhibitor and an additional components that enhance the function of the lipase inhibitor or depress the melting point of the lipase inhibitor. Therefore, because there is no teaching or suggestion in either document to use a stiffening agent such as the stiffening agents of the present invention, alone, for stiffening lipophilic substances present in the gastrointestinal tract, there can be no expectation of success for compositions comprising such a stiffening agent. Thus, the cited documents do not disclose all of the claim limitations".

In response, the stiffening agent is defined as R-COOR', R-OR', etc, the art recites, a stiffening agent with a melting point of above 33°C and a lipase inhibitor. The purpose of stiffening one or more lipohillic substances in the gastrointestinal tract of an animal – does not alter the compound nor the composition. MPEP 2112.01"Products of identical chemical composition can not have mutually exclusive properties." A chemical composition and its properties are inseparable. Therefore, if the prior art teaches the identical chemical structure, the properties applicant discloses and/or claims are necessarily present. In re Spada, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658

(Fed. Cir. 1990). Further, the composition is administered to a patient with obesity-thus an animal-human (see col. 5, lines 19 and col. 5, line 49) of de Smidt et al. and Maeder et al. (see col. 8, lines 10-13).

Thus the argument is found unpersuasive.

Regarding claims 31-36 and 71 Applicant's arguments with respect to claims 31-36 and 71 have been considered but are moot in view of the new ground(s) of rejection. Below.

The rejection of all the claims are set forth below repeated for claims 1-30 (method have been corrected to recite composition) in the and a new rejection for claims 31-36.

Claims 1-12 remain rejected under 35 U.S.C. 103(a) as being unpatentable over de Smidt et al. US 6,703,369 B1 in view of Maeder et al. US 6,730,319 B2.

With regards to claim **1** de Smidt et al. teach a pharmaceutical composition comprising (i) a glyceride ester (thus R-OR' which is per definition a stiffening agent) (see col. 1 lines 50+), R is C_{12-20}) (see col. 3, line 60), with a melting point of 37°C and (ii) a lipase inhibitor (see col. 1 lines 46+) wherein the ratio of the stiffening agent is at least 4.5:1 (see col. 4, lines 38-65) the stiffening agent varies between 05 and 90% and the lipase inhibitor varies from 1-50%. For example if the stiffening agent present in an amount of 45% and the lipase inhibitor present is 10%, the ratio therefor is 4.5:1 or 90% of the stiffening agent to 20% of the lipase inhibitor. The teachings of the recited

ranges are well within the skill of one of ordinary skill in the art to modify and determine the optimum amounts to get the maximum effect. Therefore claims **1**, **2** and **8** are obvious variation of the teaching wherein the ratio varies.

As to claim **3**, the stiffening agent is a fatty acid (see abstract) and a pharmaceutical salt as in claim **4**(see col. 2, lines 11-25), wherein the lipase inhibitor is a tetrahydrolipstatin (known as orlistat) (see col. 1 lines 10+) as in claims **5**, **6** and **10-11**.

Further, de Smidt et al. teach, with regards to claims **9- 10** the percentage of the stiffening agent varies between 0.5 and 90%. And as explained above, these wide ranges teach that or suggest any applicable range within the limitation can be use for optimization (see col. 4 lines 38-40). The composition as recited comprises of a stiffening agent and a lipase inhibitor, the reference teach a composition comprising a lipase inhibitor and a stiffening agent in a wide range of percentage, making it obvious for one of ordinary skill in the art to vary the concentration. With regards to claim **7**, wherein the lipase inhibitor is at least 0.001% and at least 0.1 % of the stiffening agent would have been obvious. (For example at least about 0.001 is interpreted to be any percentage amount that is greater than 0.001).

Maeder et al. also teach having a pharmaceutical composition containing a lipase inhibitor (see col. 4, lines 48-49), a fatty acid having a melting point equal or greater than 37°C, (see col. 1 lines 7-21 also col. 4, lines 36-37), wherein the fatty acid has a R is C_{12-20} (see col. 5, lines 37-50) wherein the fatty acid is behenic acid (see col. 5, lines 43+) as in claim 12.

The instant method differs from the de Smidt et al. teaching only in the specific ranges as discussed above and is applied to instant claim 7 also. The prior art in instant claim and did not teach behenic acid as in claim 12.

However, the determination of a ratio having the optimum index is well within the level of one having ordinary skill in the art, and the artisan would be motivated to determine the optimum amounts to get the maximum effect, hence the reference makes obvious the instant invention.

Also, one of ordinary skill would have combined the teachings of de Smidt et al. with that of Maeder et al. choose the fatty acid behenic acid because it is within the claim limitation having C equal 22 and has a melting point of above 33 degrees or greater (see supporting document www.sjlipids.com/c22.htm enclosed showing the melting point of behenic) and expect a successful result in doing so because both cited references teaches using fatty acid and substituting the specific fatty acid of Maeder et al. would have been obvious to one of ordinary skill in the art. Moreover, at the time of filing this application, one of ordinary skill in the art would have found the instant composition obvious over the reference since the reference discloses a species under the genus in the composition. Additionally, it is well settled that a reference may be relied upon for all that it would have reasonably conveyed to the skilled artisan, *In re Lamberti* 545 F.2d 747, 192 USPQ 278 (1976). Accordingly, one of ordinary skill in the art would thus have been motivated to prepare a pharmaceutical composition embraced by the disclosed reference with a reasonable expectation that the resulting composition can be used for a pharmaceutical purpose in treating a patient in need thereof. Moreover, the motivation as to why one of ordinary skill would conceive and

use similar compounds was rendered by the Court which stated in *In re Gyurik et al.*, 596 F.2d 1012, 201 USPQ 552 at 557 that:

"In obviousness rejections based in close similarity in chemical structure, the necessary motivation to make a claimed compound, and thus the prima facie case of obviousness rises from the expectation that compounds similar in structure will have similar properties". Thus, the instantly claimed composition using the compounds would have been suggested to one of ordinary skill in the art.

II. Claims 13-24 remain rejected under 35 U.S.C. 103(a) as being as unpatentable over de Smidt et al. US 6,703,369 B1 in view of Maeder et al. US 6,730,319 B2.

With regards to claim **13** de Smidt et al. teach a pharmaceutical composition comprising (i) a glyceride ester (thus R-OR' which is per definition a stiffening agent) (see col. 1 lines 50+), R is C_{12-20}) (see col. 3, line 60), with a melting point of 37°C and (ii) a lipase inhibitor (see col. 1 lines 46+) wherein the ratio of the stiffening agent is at least 1:1 (see col. 5, lines 34-37) wherein 4.24g of soya lecithin and 4.24 g of orlistat was used (see col. 7, lines 16-17). Based upon the teaching achieving the concentration in a ration of 2:1 of the stiffening agent to the lipase inhibitor is taught wherein the stiffening agent varies between 0.5 and 90% and the lipase inhibitor is from 1-50% (see col. 4, lines 38-65) claims **14, 16 and 19** are therefore taught. As taught by the reference lecithin is defined a fatty acid with the formula (see col. 4, lines 15-30). As to claim **15**, the stiffening agent is a fatty acid (see abstract), wherein the lipase inhibitor is a tetrahydrolipstatin (known as orlistat) (see col. 1 lines 10+) as in claims **17, 18**, and

23. As to claims 20-22, the claims recite at least about of the stiffening agent and the lipase inhibitor. Since the stiffening agent varies between 0.5 and 90% and the lipase inhibitor is from 1-50% (see col. 4, lines 38-65) the limitations are therefore met.

Maeder et al. also teach having a pharmaceutical composition containing a lipase inhibitor, a fatty acid having a melting point equal or greater than 37°C, (see col. 1 lines 7-21), wherein the fatty acid is calcium stearate (see col. 5, lines 37-67+) as in claims 13(ii) and **24**. One of ordinary skill in the art would have been motivated to substitute the fatty acid used by Maeder et al. with that of the claimed fatty acid calcium stearate and have the composition ratio of fatty acid to lipase inhibitor 1:1 as taught by de Smidt.

The instant composition differs from the de Smidt et al. teaching wherein the de Smidt did not teach the specific specie of fatty acid as calcium stearate but teaches a genus/generic which is cured by the Maeder et al. Applying the same logic as applied in the above rejection to the instant pharmaceutical claims, given the teaching of the prior art using fatty acid and a lipase in a composition, it would have been obvious to use the composition comprising of a fatty acid from the general teaching of de Smidt et al. wherein the fatty acid has a 14-24 carbon atoms, substituting the fatty acid of 14-24 carbons with calcium stearate as taught by Maeder et al. because the idea of doing so would have logically flow from having been individually taught in the prior art to be used in a composition and have the composition of the fatty acid to the orlistat 1:1.

III. Claims 25-30 remain rejected under 35 U.S.C. 103(a) as being as unpatentable over de Smidt et al. US 6,703,369 B1 in view of Maeder et al. US 6,730,319 B2.

With regards to claim 25 de Smidt et al. teach a pharmaceutical composition comprising (i) a glyceride ester (thus R-OR' which is per definition a stiffening agent) (see col. 1 lines 50+), R is C_{12-20}) (see col. 3, line 60), with a melting point of 37°C and (ii) a lipase inhibitor (see col. 1 lines 46+) wherein the stiffening agent is at least 5% (see col. 4, lines 38+) and from 5% to about 90% as in claim 27 is inclusive of the teaching (see col. 4, lines 38+)

As to claim 26, the stiffening agent is a fatty acid (see abstract), wherein the composition comprises a lipase inhibitor is a tetrahydrolipstatin (known as orlistat) (see col. 1 lines 10+) as in claims 29 and 30.

Maeder et al. also teach having a pharmaceutical composition containing a lipase inhibitor, a fatty acid having a melting point equal or greater than 37°C, (see col. 1 lines 7-21), wherein the fatty acid is selected from calcium sterate (see col. 5, lines 37-67+), behenic acid (see col. 5, lines 43+).

The instant composition differs from the de Smidt et al. teaching only where the specific fatty acid is selected from calcium stearate, behenic acid and mixtures thereof.

One of ordinary skill would have combined the teachings of de Smidt et al. with that of Maeder et al. choose the fatty acid calcium stearate and expect a successful result in doing so because both cited references teaches using fatty acid and substituting the specific fatty acid of Maeder et al. would have been obvious. With

regards to the limitation for administering to an animal for the purpose of stiffening one or more lipophilic substances present in the gastrointestinal tract of the animal is given no patentability weight because as explained above Products of identical chemical composition can not have mutually exclusive properties." A chemical composition and its properties are inseparable. Therefore, if the prior art teaches the identical chemical structure, the properties applicant discloses and/or claims are necessarily present. In re Spada, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658(Fed. Cir. 1990). Therefore one of ordinary skill in the art would expect the stiffening agent to stiffen one or more lipophilic substances in the gastrointestinal tract of the patient/animal with a melting point above 33 degrees.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to

consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

IV. Claims 31-36 and 71 are rejected under 35 U.S.C. 103(a) as being as unpatentable over de Smidt et al. US 6,703,369 B1 in taken with Maeder et al. US 6,730,319 B2 in view of Hug et al US 6,358,522 taken with Hird et al. WO 02/074343.

With regards to claim 31 de Smidt et al. teach a pharmaceutical composition comprising (i) a glyceride ester (thus R-OR' which is per definition a stiffening agent) (see col. 1 lines 50+), R is C_{12-20}) (see col. 3, line 60), with a melting point of 37°C and a lipase inhibitor (see col. 1 lines 46+) as in claim 35 and 71, wherein the stiffening agent is at least 5% (see col. 4, lines 38-65) as in claim 33.

As to claim 32, the stiffening agent is a fatty acid (see abstract), wherein the lipase inhibitor is a tetrahydrolipstatin (known as orlistat) (see col. 1 lines 10+) as in claims 35 and 36.

Maeder et al. also teach having a pharmaceutical composition containing a lipase inhibitor, a fatty acid having a melting point equal or greater than 37°C, (see col. 1 lines 7-21), wherein the fatty acid is selected from behenic acid (see col. 5, lines 43+) as in claim 31(ii).

Hug et al. teach a pharmaceutical compositions containing an inhibitor of gastrointestinal lipases, one (or more) additive(s) of the group consisting of substantially non-digestible food grade thickeners and emulsifiers, and excipients (see

abstract). wherein the compositions are useful for inhibiting anal oil leakage (see col. 1, lines 56-57).

Hird et al. teach composition comprising a non-digestible, non-absorbable, open –celled polymeric foam (see abstract and page 5 second para. from the bottom) wherein the compositions are useful for inhibiting lipids or lipophillic materials present in the GI for anal leakage see pages 8 (last para. bridging page 9).

One of ordinary skill would have combined the teachings of de Smidt et al. with that of Maeder et al. choose the fatty acid calcium stearate and expect a successful result in doing so because both cited references teaches using fatty acid and substituting the specific fatty acid of Maeder et al. would have been obvious.

Further on of skill would be motivated to combine the teachings of de Smidt et al. taken with Maeder et al in view of Hug et al. for the absorption of oil as taught by Hug et al. in the treatment of anal oil leakage. Also, one of ordinary skill in the art would be motivated to combine the cited art add a non-digestive, non-absorbable, open celled polymeric foam because this composition can be used to treat anal leakage as taught by Hug et al. (see col. 1, lines 58-66) and as taught by Hird et al. these open celled forms are non-digestable (see page 9, last para) wherein the open celled foams inhibit digestion by the gastric fluid).

Thus, the claimed invention was prima facia obvious to make and use at the time it was made.

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shirley V. Gembeh whose telephone number is 571-272-8504. The examiner can normally be reached on 8:30 -5:00, Monday- Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel can be reached on 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Ardin H Marschel 5/13/07

SVG
5/3/07

ARDIN H. MARSCHEL
SUPERVISORY PATENT EXAMINER